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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,068	09/20/2001	Hazire Oya Alpar	41577/263898	6302

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EXAMINER

FIELD, TAMMY K

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,068

Applicant(s)

ALPAR ET AL.

Examiner

Tammy K. Field

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13 drawn to a pharmaceutical composition comprising a biologically active agent, adjuvant chemical, and pharmaceutically acceptable carrier or diluent, the first appearing technical feature.

Group II, claim(s) 14, drawn to a method of producing a prophylactic or therapeutic vaccine, a first method of use of a polymeric material.

Group III, claim(s) 15-17, drawn to a method of protecting a mammal against infection, the first method of use of the first technical feature.

Group IV, claim(s) 18-23, drawn to a microsphere, the second technical feature.

Group V, claim(s) 24 and 25, drawn to the use of a chemical or adjuvant chemical, a second method of use of the first technical feature.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of claim 1 is a pharmaceutical composition comprising: (i) a biologically active agent, (ii) an adjuvant chemical, and (iii) a pharmaceutically acceptable carrier. The art of Duncan, J.D., *et al.* (International Application WO 94/20070 published September 15, 1994) teach a four component composition comprising: (i) a biologically active

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agent, *e.g.* immunogens or antigens at page 4, paragraph 1- page 5, paragraph 1, (ii) an adjuvant chemical, *e.g.* polyarnithine or vitamin A at page 9, paragraph 1-page 10, paragraph 1, and (iii) a pharmaceutically acceptable carrier, *e.g.* mucoadhesive at page 6, paragraph 1. Also pertaining to the applicant's instant claim 1 (iii), Duncan, J.D., *et al.* further teaches the immunogen, mucoadhesive and adjuvant can be combined with a pharmaceutically acceptable liquid vehicle, such as water at page 11, paragraph 1. Duncan, J.D., *et al.* also teaches that an enhancement in immune response is observed when the adjuvant is combined with the immunogen and mucoadhesive, (iv) *e.g.* delivery system or vaccine for oral administration, at page 10, paragraph 2 – page 11, paragraph 3. Therefore, Unity of Invention is not fulfilled because there is not a technical feature that is “special”, in that the technical feature does not define a contribution over the art. As such, the pharmaceutical composition comprising: (i) a biologically active agent, (ii) an adjuvant chemical, and (iii) a pharmaceutically acceptable carrier lacks unity of invention with the methods of use set forth in Inventions III and V. Inventions II and IV do not require the use of the technical feature of Group I and since they define separate technical features as set forth supra, Inventions II and IV lack unity of invention because they do not form a single general concept. Furthermore, different technical features of Inventions II and IV do not rely upon the technical feature of Inventions I and therefore also lack unity of invention because they lack a technical feature in common within the meaning of PCT Rule 13.2.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

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Invention I

- A. a polyamino acid (Claim 1)
- B. a water soluble vitamin or vitamin derivative (Claim 1)
- C. positively charged cationic pluronics (Claim 1)
- D. a clathrate (Claim 1)
- E. a complexing agent (Claim 1)
- F. cetrinides (Claim 1)
- G. an S-layer protein (Claim 1)
- H. Methyl-glucamine (Claim 1)

Invention V

- I. a polyamino acid (Claims 24 and 25)
- J. a water soluble vitamin or vitamin derivative (Claims 24 and 25)
- K. positively charged cationic pluronics (Claims 24 and 25)
- L. a clathrate (Claims 24 and 25)
- M. a complexing agent (Claims 24 and 25)
- N. cetrinides (Claims 24 and 25)
- O. an S-layer protein (Claims 24 and 25)
- P. Methyl-glucamine (Claims 24 and 25)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:
Invention I – claim 1, and Invention V – claims 24 and 25.

The following claim(s) are generic: 1 and 24.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Invention I, claim 1 (ii) and Invention V adjuvant chemical or chemical species lack a common core feature/structure and therefore fail to share a substantial technical feature disclosed as being essential to that utility. As such, each of the different technical features recited as Invention I-V lack a corresponding technical feature and by definition do not meet the requirements of PCT Rule 13.2.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). If applicant elect Invention I or V, they should also elect a species as set forth supra.

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Tammy K. Field

September 22, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600